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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/21/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/888,721

Applicant(s)

HUSTON ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 March 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Upon further review and reconsideration, the previous restriction requirement is vacated in light of the new restriction requirement set forth in this action.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, 4-8, 16-29, and 52 are drawn to a gene-delivery compound comprising a single chain binding peptide and a nucleic acid binding moiety, classified in class 424, subclass 134.1.
- II. Claims 1 and 3, drawn to a gene-delivery compound comprising a single chain binding peptide, a nucleic acid binding moiety, and a nucleic acid, classified in class 530, subclass 388.21.
- III. Claims 1,9, and 13, drawn to a gene-delivery compound comprising a single chain binding peptide, a nucleic acid binding moiety, and an effector segment that binds reversibly with nucleic acids, classified in class 530, subclass 387.3.
- IV. Claims 1, 10 and 14, drawn to a gene-delivery compound comprising a single chain binding peptide, a nucleic acid binding moiety, and an effector segment that facilitates endosomal escape or avoidance, classified in class 530, subclass 402.
- V. Claims 1 and 11, drawn to a gene-delivery compound comprising a single chain binding peptide, a nucleic acid binding moiety, and an effector

segment that facilitates non-endosomal transport in a cell, classified in class 530, subclass 388.22.

- VI. Claims 1,12, and 15, drawn to a gene-delivery compound comprising a single chain binding peptide, a nucleic acid binding moiety, and an effector segment that facilitates entry into a nucleus, classified in class 530, subclass 388.26.
- VII. Claims 30-31, 33-41, 49-51, drawn to a gene delivery compound comprising a single chain binding peptide and a lipid associating moiety, classified in class 530, subclass 354.
- VIII. Claims 30 and 32, drawn to a gene delivery compound comprising a single chain binding peptide, a lipid associating moiety, and a nucleic acid, classified in class 424, subclass 181.1.
- IX. Claims 30, 42 and 46, drawn to a gene delivery compound comprising a single chain binding peptide, a lipid associating moiety, and an effector segment capable of associating with a nucleic acid, classified in class 424, subclass 182.1.
- X. Claims 30, 43, and 47, drawn to a gene delivery compound comprising a single chain binding peptide, a lipid associating moiety, and an effector segment that facilitates endosomal escape, classified in class 530, subclass 402.
- XI. Claims 30 and 44, drawn to a gene delivery compound comprising a single chain binding peptide, a lipid associating moiety, and an effector

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segment that facilitates non-endosomal transport, classified in class 530, subclass 388.22.

XII. Claims 30, 45, and 48, drawn to a gene delivery compound comprising a single chain binding peptide, a lipid associating moiety, and an effector segment that facilitates entry into the nucleus of a cell, classified in class 530, subclass 388.26.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions groups I-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ one from the other because the products claimed have different structure, consist of different elements and have different modes of use. Furthermore, the structures claimed have different chemical moieties that are considered distinct and have different effects one from the other.

5. Because these inventions are distinct for the reasons given above and the search required for Groups I-XIII are not required one for the other, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. If applicant elects group I for prosecution on the merits, applicant must select one:

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- i. marker from: erbB2, erbB3, erbB4, p53, p21 ras, transferring receptor, Lewis Y antigen, carcinoembryonic antigen, epidermal growth factor, or MUC1;
  - ii. nucleic acid binding moiety from : salmon protamine, subfragment of salmon protamine, human histone H1, subfragment of human histone H1, human protamine, subfragment of human protamine, HMG, or polylysine;
  - iii. therapeutic gene from: lymphokine, tumor necrosis factor, intrabody, tumor suppressor genes, p53, proapoptotic genes, suicide genes, prodrug converting genes, HSV-TK, or anti-angiogenic genes; and
  - iv. conjugate from: C6ML3-9 sFv'-H1, C6ML3-9 sFv'-P1 or C6ML3-9 sFv'- SP.
- b. If applicant elects group VII for prosecution on the merits, applicant must select **one**:
- i. marker from: erbB2, erbB3, erbB4, p53, p21 ras, transferring receptor, Lewis Y antigen, carcinoembryonic antigen, epidermal growth factor, or MUC1; and
  - ii. lipid associating compound from: linear, branched, cyclic, or polycyclic.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6,7,22-29, and 35-36 are generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim


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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Christopher Yaen  
Art Unit 1642  
May 6, 2003